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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/817,547    03/27/97    ADERMANN    K    07856-0007

JONES & ASKEW  
191 PEACHTREE STREET 37TH FLOOR  
ATLANTA GA 30303-1769

HM12/0315

EXAMINER

KEMMERER, E

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

03/15/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/817,547

Applicant(s)  
Adermann et al.

Examiner  
Elizabeth C. Kemmerer

Group Art Unit  
1646



☒ Responsive to communication(s) filed on 21 Dec 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 6-21 is/are pending in the application.

Of the above, claim(s) 6 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 7-21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 6-21 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Status of Application, Amendments, And/Or Claims*

The amendment filed 21 December 1998 (Paper No. 14) has been entered in full. Claims 1-5 are canceled. Claim 6 remains pending and withdrawn from consideration by the examiner as being directed to a non-elected invention. Newly submitted claims 7-21 are pending and under examination.

### *Withdrawn Objections And/Or Rejections*

Applicant has now complied with all of the requirements for receiving the benefit of priority from PCT/EP95/03757 under 35 U.S.C. § 371.

The application is now fully in compliance with the sequence rules, 37 CFR 1.821-1.825.

The objection to claims 3-5 for informalities as set forth at p. 4 of the previous Office Action (Paper No. 12, 13 August 1998) is *withdrawn* in view of the canceled claims (Paper No. 14, 21 December 1998).

The rejection of claim 5 under 35 U.S.C. §§101 and 112, second paragraph, as set forth at pp. 4-5 of the previous Office Action (Paper No. 12, 13 August 1998) is *withdrawn* in view of the canceled claim (Paper No. 14, 21 December 1998).

The rejection of claims 3-5 under 35 U.S.C. § 112, second paragraph, as set forth at p. 5 of the previous Office Action (Paper No. 12, 13 August 1998) is *withdrawn* in view of the canceled claims (Paper No. 14, 21 December 1998).

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The rejection of claims 3-5 under 35 U.S.C. § 112, first paragraph, as set forth at pp. 5-7 of the previous Office Action (Paper No. 12, 13 August 1998) is *withdrawn* in view of the canceled claims (Paper No. 14, 21 December 1998). However, the newly submitted claims are rejected under a similar basis. Please see section on 35 U.S.C. § 112, first paragraph, below.

The rejection of claims 3-5 under 35 U.S.C. § 102(b) as being anticipated by any one of Nussbaum et al. or Tampe et al. as set forth at pp. 8-9 of the previous Office Action (Paper No. 12, 13 August 1998) is *withdrawn* in view of the canceled claims (Paper No. 14, 21 December 1998). Also, neither reference suggests that the disclosed antibodies recognize only *active* hPTH peptides, which is required by the newly submitted claims.

***35 U.S.C. § 112, First Paragraph***

Claims 7-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Newly submitted claims 7-16 are directed to compositions for detecting active hPTH comprising antibodies or fragments of antibodies that are capable of binding active hPTH. Newly submitted claims 17-21 are directed to immunological methods of detecting active hPTH utilizing the same antibodies or fragments thereof as well as a second antibody or fragment thereof. The specification discloses several fragments of hPTH, and states that antibodies can be prepared against these peptides which apparently recognize active hPTH fragments (such as hPTH(1-37)) and not

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inactive hPTH peptides (such as hPTH(1-84)), although this is not clear from the specification. The specification provides general methods for making hPTH peptides and antibodies which recognize them; however, the specification does not disclose how to make antibodies which bind active hPTH but not inactive hPTH. It is also hard to theorize *how* such antibodies would identify one and not the other. For example, the disclosed peptides hPTH(1-10), hPTH(2-9), etc., disclosed at pp. 3-5 are all comprised within the inactive hPTH(1-84). If an antibody recognized an epitope in one of these short fragments, it would also reasonably be expected to recognize the longer peptide in which the epitope is comprised. Furthermore, there is an absence of working examples directed to such antibodies. The nature of the invention is complex, given the complexity of antibody structure, antibody-epitope interaction, and prediction of protein folding structure (see Bowie et al. and Ngo et al.). The prior art indicates that algorithms designed to identify epitopes have proven highly unpredictable, with algorithms both identifying sequences as epitopes which did not prove to be so, and also failing to identify true epitopes (Daniel et al., of record). Finally, the breadth of the claims is large, considering claims 7, 15, 17 and 21 do not specify the particular epitope or antibody required to achieve the effect. For all of these reasons, undue experimentation would have been required of the skilled artisan to make and use the claimed invention in its full scope.

Applicant argues (pp. 7-8) that the rejection should be withdrawn in view of the canceled claims. The rejection has been withdrawn for the canceled claims. Applicant also urges that the specification enables the newly submitted claims, especially considering the examiner's statement in the previous Office Action that the specification is enabling for antibodies raised against the disclosed

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peptides and for methods of detecting hPTH using same. This has been fully considered but is not deemed to be persuasive, because the examiner's previous statement does not contradict the instant rejection. Although the specification is enabling for antibodies raised against the disclosed peptides and for methods of detecting hPTH using same, it is not enabling for antibodies which recognize only *active* hPTH or for methods of detecting *active* hPTH using same, which is required by the claims.

***35 U.S.C. § 112, Second Paragraph***

Claims 7-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-21 are vague and indefinite due to the recitation of an antibody which is "capable of" binding a peptide. It is not clear what conditions are required to allow for such binding, such that it is not clear whether the recited antibodies bind the peptides or not. It is suggested that Applicant consider amending the claims to recite "...antibodies or fragments of antibodies [that are capable of selectively binding to] which selectively bind active hPTH", which is one way to overcome the rejection. Additionally, the method steps of claims 17-21 do not achieve the goal set forth in the preamble (i.e., detecting *active* hPTH). Specifically, is it not clear what result is required from contacting the sample with the second antibody or antibody fragment capable of binding an epitope of hPTH which is different from that bound by the first antibody.

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***Claim Objections***

Claims 7-17 are objected to because of the following informalities: Claims 7-16 are improper composition claims. The claims are directed to a composition, which by definition contains more than one compound, yet only one compound is required. Amending the claims to recite "and a carrier" is one way to resolve this issue. Independent claims 7, 15 and 17 recite the abbreviation "hPTH" without providing a definition thereof. In the interest of clarity, it is suggested that Applicant adopt the following in the independent claims "...human parathyroid hormone (hPTH)...". Additionally, the word "of" appears to be missing after "capable". Appropriate correction is required.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claim 6 drawn to an invention nonelected with traverse in Paper No.

11. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

~~ELIZABETH KEMMERER~~

ELIZABETH KEMMERER  
PRIMARY EXAMINER

ECK  
March 11, 1999